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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,290	10/15/2003	Ivan Osorio	011738.00134	8970

70467 7590 05/05/2009

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EXAMINER	
HOLMES, REX R	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
05/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,290	OSORIO ET AL.	
	Examiner	Art Unit	
	REX HOLMES	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-21,23,28,29,32,37,38 and 43-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13-21,23,28,29,32,37,38 and 43-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/14/08;12/12/08;2/25/09;2/26/09;3/24/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's arguments, see Remarks, filed 2/13/09, with respect to the restriction requirement of 1/13/09 have been fully considered and are persuasive. The restriction of claims 1-11, 13-21, 23, 28-29, 32, 37-38 and 43-48 has been withdrawn.

Claim Rejections - 35 USC § 102/103

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-11, 13-21, 23 and 43-46 are rejected under 35 U.S.C. 102(b) as anticipated by Fischell et al. (U.S. Pat. 6,128,538 hereinafter "Fischell") or, in the alternative, under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (U.S. Pat. 6,128,538 hereinafter "Fischell").

6. In reference to claims 1-2, 6, 8, 13-15, 19-20, 43-46, Fischell discloses method for treating neurological disorders specifically epileptic seizures, utilizing an implantable therapy element that is coupled to an implantable monitoring element (e.g. Abstract; Fig.2, Elements 30, 40). Fischell further discloses that electrodes for sensing and stimulation are connected to the monitoring and therapy elements and a processor (e.g. Col. 2, ll. 63-67 & Col. 3., ll. 1-8, Fig. 2), and that the sensing unit monitors EEG activity (e.g. Col. 8, ll. 42-45). Fischell also discloses that once a disorder is sensed the stimulation starts (e.g. Col. 12, ll. 41-54). Fischell further discloses that the detection algorithm contains an event density counter/detector algorithm that determines if there have been enough events in the most recent time period to notify the central processor that a real event has taken place to eliminate the number of false positives by eliminating short uncorrelated bursts (e.g. Col. 19, ll. 19-32). It is further noted that time period can be in the range of ½ to 100 seconds (e.g. Col. 19, ll. 23-25).

7. In reference to claims 3, 16, Fischell discloses the use of an implantable drug delivery system utilizing a catheter as the therapy delivery element, and the sensing unit is comprised of electrode sensors (e.g. Col. 25, ll. 53-67 & Col. 26, ll. 1-3).

8. In reference to claims 4-5, 7 and 9, Fishcell discloses that the treatment of neurological diseases such as epilepsy, migraine headaches and Parkinson's disease (Abstract). Fischell further discloses that the use of implanted electrodes to detect the onset of seizures (e.g. Col. 2, ll. 41-56).

9. In reference to claim 10, 23, Fischell discloses that once a event is detected a timer starts to allow the device to determine if enough events occur to limit the number of false positives (e.g. Col. 19, ll. 13-46).

10. In reference to claims 17 and 18, Fischell discloses that the device could contain an external control system (e.g. Fig. 24; Col. 32, ll. 4-15).

11. In the alternative, Regarding claims 1-11, 13-21, 23 and 43-46, Fischell discloses the claimed invention including a delay to stabilize the sensing algorithm to eliminate false positive and make sure that it is sensing events correctly. Fischell discloses the claimed invention except for explicitly stating that the therapy device is activated once implanted. It is obvious and well known to have some time for the algorithm to stabilize such as 2 seconds so the algorithm can correctly detect a seizure. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the neurological stimulator as taught by Fischell to include a delay to stabilize the sensing algorithm after implantation since such a modification would provide the neurological stimulator with a delay after initialization for providing the

predictable result of providing the patient with time to prepare for the therapy and stabilize the sensing algorithm.

12. Similarly, Fischell discloses a neurological stimulator with a delay to stabilize the sensing algorithm to eliminate false positive and make sure that it is sensing events correctly. Fischell provides the predictable result of a neurological stimulator with a stimulation delay timer after the activation of therapy to allow the patient time to prepare for the therapy and to stabilize the sensing algorithm.

13. It is noted that block counts are described in the Applicant's specification in paragraph 138 as occurring at a fixed rate of 48 milliseconds. Thus, block counts are a fixed unit of time and a quantity of block counts is equivalent to a period of time.

14. In regards to claim 11 & 21, the Fischell teaches the claimed invention but does not disclose expressly the 30-minute time frame. It would have been an obvious matter of choice to a person of ordinary skill in the art to modify the neurostimulation device as taught by Fischell with a time frame in which the device can acquire data after implantation, because the applicant has not disclosed that the 30- minute time frame provides an advantage, is used for a particular purpose, or solves a stated problem by stating that "the time period is a function of the background window length and may vary in duration" (e.g. see paragraph [137] of applicant's disclosure). One of ordinary skill in the art furthermore would have expected applicant's invention to perform equally as well in conjunction with the Fischell neurostimulator because it provides a timeframe in which the Fischell device can acquire data after implantation to allow for the determination of proper stimulation parameters and since it appears to be an arbitrary

design consideration which fails to patentably distinguish over the Fischell system. Therefore it would have been obvious matter of design choice to modify the Fischell system to obtain the invention specified in the aforementioned claims.

15. Claims 28-29, 32 and 37-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Snell et al. (U.S. Pub. 2002/0143372 hereinafter "Snell") or, in the alternative, under 35 U.S.C. 103(a) as being unpatentable over Snell.

16. Regarding claims 28-29, 32 and 37-38, Snell discloses an implanting a therapy delivery element in the body (e.g. 20, 30), coupling it to a therapy device (e.g. 10), and programming the device with custom parameters. Snell further discloses that the device verifies the parameters to see if they within acceptable levels and if not it sends an error preventing the therapy device from being configured (e.g. ¶46). Snell further goes on to say that the system can use a wide variety of error detection techniques depending upon the particular parameters that are set.

17. In the alternative, Snell does not expressly state that it checks for stimulations per detection period, stimulations per detection cluster, or on time, however, Snell states that the system can use a wide variety of error detection techniques depending upon the particular parameters that are set and they did not list the particular parameters or error checking techniques as the list was so exhaustive. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the error handling techniques of Snell to look at the programmable parameters associated with stimulations per detection period, stimulations per detection cluster, and on time to provide the predictable results of checking the programmable parameters to

make sure that they are within thresholds to make sure that the patient, device and battery are not harmed.

18. Claims 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell as applied to claim 29 above, and further in view of Archer et al. (U.S. Pat. 6,690,974 hereinafter "Archer").

19. Regarding claims 47-48, Snell teaches the claimed invention except for stating that the stimulation has a charge density less than 30μC/cm^2/phase. However, Archer discloses that a charge density of less than 25μC/cm^2/phase is used in order to prevent neural tissue damage. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the system of Snell to use a stimulation signal with a charge density of 25μC/cm^2/phase or less as taught by Archer in order to provide the predictable result of stimulating the brain without providing neural damage.

Response to Arguments

20. Applicant's arguments filed 1/13/09 regarding the rejections have been fully considered but they are not persuasive. The Applicant argues that Fischell does not disclose preventing therapy for a period of time to allow for the seizure detection algorithm to stabilize. Fischell discloses that it is for epileptic seizures (Abstract; Col. 2, ll. 41-56; Col. 5, ll. 15-25). Fischell further discloses that once it starts sensing and determines that there might be an event, it starts a counter and determines if a number of sensed events occur in a specific amount of time and if so it delivers therapy, therefore therapy is inhibited until that time. While Fischell does start a counter it only

counts the number of events for a specified period of time. This time is equivalent to the Applicants quantity of block counts as discussed above. It is noted that block counts are described in the Applicant's specification in paragraph 138 as occurring at a fixed rate of 48 milliseconds. Thus, block counts are a fixed unit of time and a quantity of block counts is equivalent to a period of time.

21. The Applicant further argues that waiting a specified period of time to limit false positives does not allow for stabilization to occur. The Applicant further points out that since Fischell does not state that the step of waiting a period of time to allow for the removal of false positives is specifically a stabilization period, so it can not be a stabilization period. The Examiner respectfully disagrees. Fischell discloses that the detection algorithm contains an event density counter/detector algorithm that determines if there have been enough events in the most recent time period to notify the central processor that a real event has taken place to eliminate the number of false positives by eliminating short uncorrelated bursts (Col. 19, ll. 19-32). If the signal contained short uncorrelated bursts the signal would not be stable and would contain false positives. By eliminating false positives the system is allowing a period of time for the signal to stabilize and thus allowing for the detection algorithm to have a stabilized signal, thus effectively stabilizing the detection algorithm.

22. The Applicant further argues that it is directed to preventing therapy from occurring immediately after the device has been activated. It is further noted that claims do not define when activation of therapy starts, in this case it determined that the therapy starts when the first sensed event is found and the counter starts.

23. Applicant's arguments, see Remarks, filed 10/14/08, with respect to the rejection(s) of claim(s) 28-29, 32, 37-38 and 47-48 under Fischell in view of Aimone have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Snell.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REX HOLMES whose telephone number is (571)272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./ /George R Evanisko/

Examiner, Art Unit 3762 Primary Examiner, Art Unit 3762